

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

NICHOLAS SKIADAS, *individually and on behalf  
of all others similarly situated,*

Plaintiffs,

-against-

ACER THERAPEUTICS INC., CHRIS  
SCHELLING, and HARRY PALMIN,

Defendants.

Case No. 1:19-CV-6137-GHW

Oral Argument Requested

**DEFENDANTS' MOTION FOR RECONSIDERATION OF THE JUNE 16, 2020  
MEMORANDUM OPINION AND ORDER ON DEFENDANTS'  
MOTION TO DISMISS THE SECOND AMENDED COMPLAINT**

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## PRELIMINARY STATEMENT

Defendants Acer Therapeutics Inc. (“Acer”), Chris Schelling, and Harry Palmin (collectively, “Defendants”) ask this Court to reconsider its Order dated June 16, 2020 (Dkt. 54) (the “Order”) denying in part Defendants’ motion to dismiss. Defendants respectfully submit that the Order contains several instances of clear error. The Order:

- Relied incorrectly on a District of Connecticut case addressing reasonable reliance, *not* falsity, *Umbach v. Carrington Inv. Partners*, No. 3:08-CV-484(EBB), 2009 WL 413346 (D. Conn. Feb. 18, 2009), as the sole legal authority for its erroneous holding that ambiguity can suffice to plead falsity;
- Applied an incorrect standard for assessing allegations of motive for purposes of pleading scienter, contrary to a long line of Second Circuit cases, including *Kalnit v. Eichler*, 264 F.3d 131 (2d Cir. 2001); and
- Used an incorrect “plausibility” standard for pleading scienter, contrary to the Supreme Court’s decision in *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007). And while the Court relied heavily on *In re Mannkind Secs. Actions*, 835 F. Supp. 2d 797 (C.D. Cal. 2011), to find plausibility, recent authority from the Ninth Circuit, *Nguyen v. Endologix, Inc.*, No. 18-56322, 2020 WL 3069776 (9th Cir. Jun. 10, 2020), rejected plausibility on allegations very close to those here.

Correction of any one of these errors supports dismissal of the remaining claims in this case.

### Falsity

Despite holding that “context weighs in favor” of Defendants’ interpretation of the challenged statements (Dkt. 54, at 16-17), the Order erroneously held that Plaintiff had adequately pled the statements were false, finding that “[b]ecause the challenged statements are ambiguous, the Court cannot dismiss [Plaintiff’s] claims based on those statements as a matter of law.” (Dkt. 54, at 17 (citing *Umbach*, 2009 WL 413346, at \*6).) This is clear error. In the Second Circuit, under the heightened pleading standards of Rule 9(b) and the Private Securities Litigation Reform Act (“PSLRA”), statements are false when “taken *together and in context* [they] would have misled a reasonable investor.” *Rombach v. Chang*, 355 F.3d 164, 172 n.7 (2d

Cir. 2004) (emphasis added). Neither Plaintiff nor the Court cited any cases calling this Second Circuit authority into doubt, nor any authority to support the novel proposition that ambiguity constitutes falsity for purposes of pleading federal securities fraud. It does not, and the clause the Order cites from *Umbach*—a case Plaintiff never cited—addresses reasonable reliance, *not falsity*.

### Scienter

The Order also made two crucial errors in assessing the adequacy of Plaintiff's scienter allegations. First, on the issue of motive to commit fraud, the Court disregarded the controlling law cited by Defendants (Dkt. 50, at 18-19; Dkt. 53, at 7-8) and instead relied on *Frater v. Hemispherx Biopharma, Inc.*, 996 F. Supp. 2d 335 (E.D. Pa. 2014), an Eastern District of Pennsylvania decision, to erroneously hold that Defendants were motivated to commit fraud by virtue of their need to raise capital to avoid bankruptcy. (Dkt. 54, at 21.) Notably, *Frater* does not stand for this proposition, and it is also contravened by extensive clear and controlling authority from this Circuit holding that a motive to raise money, even when needed to avoid bankruptcy or to ensure the survival of a company, does not create an inference of scienter.

Second, the Order repeatedly stated that Plaintiff alleged a “plausible” inference of scienter. But that is not the standard under the PSLRA and controlling law. The Supreme Court has expressly held that “an inference of scienter must be *more than merely plausible* or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent.” *Tellabs*, 551 U.S. at 309 (emphasis added). Furthermore, the Court relied extensively on the Central District of California's decision in *In re Mannkind Secs. Actions*, 835 F. Supp. 2d 797, to find that Plaintiff's “not wholly illogical” (Dkt. 54, at 22) scienter allegations were plausible, but recent intervening authority from the Ninth Circuit expressly rejected a

theory of scienter essentially identical to Plaintiff's here. *Nguyen*, 2020 WL 3069776. When analyzed under the required standard, Plaintiff's theory of scienter, which the Court found merely "plausible," is neither cogent nor compelling, a further independent ground for dismissal.

For any of these reasons, the Court should reconsider its ruling and dismiss this case.

### **ARGUMENT**

A motion for reconsideration should be granted when the moving party identifies "an intervening change of controlling law, the availability of new evidence, or the need to correct a clear error or prevent manifest injustice." *Kolel Beth Yechiel Mechil of Tartikov, Inc. v. YLL Irrevocable Trust*, 729 F.3d 99, 104 (2d Cir. 2013). Here, there are multiple instances of clear error, each of which provides grounds for reconsideration, as well as intervening authority from the Ninth Circuit that rejects the scienter theory in *In re Mannkind Secs. Actions*, 835 F. Supp. 2d 797, cited in the Order. First, the Order applied an incorrect standard in determining whether Plaintiff adequately pled a false statement, mistakenly relying on a case about reliance. Second, the Order disregarded Second Circuit authority holding that Plaintiff's theory of motive is insufficient as a matter of law to plead scienter. Finally, the Order incorrectly applied a lower, "plausibility" standard for pleading scienter rather than the heightened "cogent and compelling" inference standard required by the Supreme Court and the PSLRA. Correction of any one of these errors supports dismissal of the SAC.

#### **I. THE ORDER APPLIES THE WRONG STANDARD FOR ASSESSING FALSITY AND IGNORES CONTROLLING LAW**

The Court held that Plaintiff adequately pled falsity based on a finding that the challenged statements were ambiguous. But ambiguity does not suffice to plead falsity. Plaintiff challenges Defendants' statements that the FDA "agreed that additional clinical development is not needed and stated that [Acer] may submit a 505(b)(2) NDA for EDSIVO" (SAC ¶¶ 106, 108,

112), claiming that the statements refer to an agreement to *approve* the EDSIVO NDA.

Defendants contend that the plain language of the challenged statements refers to *submission* of the NDA, as the statements do not refer to approval. *See* Dkt. 54, at 15-16. The Court held that “Defendants are correct that this context weighs in favor of construing the statements to be about submission, not approval,” but nonetheless “construe[d] them as referring to EDSIVO approval” for purposes of determining whether Plaintiff adequately pled a false statement, on the grounds that the Court must resolve ambiguities in Plaintiff’s favor at this stage. *Id.* at 16-17.

This was clear error. Not only did Plaintiff never allege in the SAC or argue in his briefing that the challenged statements were ambiguous, but under the heightened pleading standards of Rule 9(b) and the PSLRA, the Second Circuit has held that statements are false or misleading only when, “taken *together and in context*, [they] would have misled a reasonable investor.” *Rombach*, 355 F.3d at 172 n. 7 (emphasis added). This standard does not encompass resolving alleged ambiguity in a plaintiff’s favor to find falsity, and the sole case the Court cited in support of this novel proposition, *Umbach v. Carrington Inv. Partners*, 2009 WL 413346—a case cited by neither party—does not hold otherwise.

In *Umbach*, the District of Connecticut stated that ambiguity can be read in a plaintiff’s favor to establish *reliance*. The *Umbach* court did *not* rule that ambiguity can establish *falsity*. In *Umbach*, the court found that plaintiff “made sufficient allegations of misstatement” based on allegations that defendants made a verbal representation, later confirmed in a side letter, about amendments to a hedge fund partnership agreement, but failed to disclose that these amendments would not apply in certain circumstances. *Id.* at \*5. Defendants moved to dismiss on the grounds that plaintiff could not have reasonably relied on the false verbal statement based on Second Circuit precedent holding that sophisticated investors cannot claim reasonable reliance if



an agreement has an integration clause and does not contain the alleged misrepresentation. *Id.* The court declined to dismiss on reliance grounds, holding that ambiguities in the partnership agreement and side letter, read in plaintiff's favor, prevented a finding that plaintiff could not have relied on the alleged misrepresentation. *Id.* at \*6. *Umbach's* statement regarding reliance does not support this Court's holding that ambiguity *in the challenged statement* should be read in Plaintiff's favor in order to establish *falsity*. And Plaintiff himself cites no authority to support this proposition.

Consistent with the heightened pleading standards of Rule 9(b) and the PSLRA, courts have found ambiguities to count *against* finding falsity. *See, e.g., Smith v. Antares Pharma, Inc.*, No. 17-CA-8945(MAS)(DEA), 2019 WL 2785600, \*9 (D.N.J. July 2, 2019) ("Because Plaintiff relies on [confidential witness 1's] allegations to show that Defendants' statements were materially false and misleading . . . the ambiguity of CW1's allegations is significant in light of the PSLRA's high standard. The Court, therefore, must steeply discount CW1's allegations."); *Welgus v. TriNet Grp., Inc.*, No. 15-CV-03625(BLF), 2017 WL 6466264, at \*14 (N.D. Cal. Dec. 18, 2017) ("Plaintiff's argument that Defendants somehow 'created ambiguity' in their public statements, despite clear disclosures throughout the Class Period . . . is not sufficient to satisfy Rule 9(b) or the PSLRA's requirement that a plaintiff plead contemporaneous and specific facts indicating why the challenged statements were false."), *aff'd*, 765 F. App'x 239 (9th Cir. 2019); *Kelly v. Elec. Arts, Inc.*, No. 13-CV-05837(SI), 2015 WL 1967233, at \*7–8 (N.D. Cal. Apr. 30, 2015) (declining to find falsity where plaintiff's "allegations [did] not demonstrate that the [challenged statement] has any precise meaning"); *Lomingkit v. Apollo Educ. Grp. Inc.*, 275 F. Supp. 3d 1139, 1155 (D. Ariz. 2017) (holding that

plaintiff failed to adequately plead falsity of defendants’ statements regarding its “rollout” where the term had no consistent definition and plaintiffs failed to allege one).

Plaintiff’s entire falsity claim—indeed, his entire case—now rests on the Court’s finding that ambiguity supports falsity, even where the statement’s context favors Defendants’ reading. Plaintiff cited no authority in support of this proposition, and *Umbach* does not support it either. Given its finding on context (Dkt. 54, at 16), the Court should construe the challenged statements as about submission when assessing the element of falsity. And there is no doubt that a statement about submission of the NDA is not false. Plaintiff does not so allege, and the allegations in the SAC make clear that Defendants’ statements regarding submission were true: Defendants submitted the NDA, and the FDA accepted it for filing and priority review, with no further clinical studies. SAC ¶ 100. For that reason, the Court should reconsider its ruling and dismiss the SAC for failure to plead falsity.

## **II. THE ORDER ALSO APPLIES THE WRONG STANDARD FOR ASSESSING SCIENTER AND IGNORES CONTROLLING LAW**

### **A. The Ruling that Plaintiff Adequately Pled Motive Based on Allegations of Defendants’ Need to Raise Capital is Clear Error**

The Court recognized that there were no insider stock sales “or any other evidence of pecuniary gain by company insiders at shareholders’ expense.” (Dkt. 54, at 21 (quoting *In re N. Telecom Ltd. Secs. Litig.*, 116 F. Supp. 2d 446 (S.D.N.Y. 2000)).) But the Court nonetheless held that Plaintiff adequately pled scienter based on allegations that Defendants were motivated to commit fraud because Acer needed to raise capital to fund its operations and continue operating as a going concern.

This finding disregards a mountain of case law in this Circuit holding that allegations that Defendants were motivated by a desire to continue operating as a going concern or to avoid bankruptcy—to use the Court’s words, a desire to “survive” or to avoid “go[ing] belly up” or

“certain failure” (Dkt. 54 at 21)—are unequivocally *insufficient* to support an inference of scienter:

- *In re Elan Corp. Sec. Litig.*, 543 F. Supp. 2d 187, 216 (S.D.N.Y. 2008) (granting motion to dismiss suit against a biotechnology company, holding that “[a]ny corporation would be motivated to make a profit, **to avoid bankruptcy**, or to finance the successful launch of a promising product. . . . These allegations do not support an inference of scienter.”) (emphasis added);
- *In re PXRE Grp., Ltd., Sec. Litig.*, 600 F. Supp. 2d 510, 532 (S.D.N.Y.), *aff’d sub nom.*, *Condra v. PXRE Grp. Ltd.*, 357 F. App’x 393 (2d Cir. 2009) (desire to “raise money that is ‘desperately needed’ or **necessary ‘to protect the very survival’ of a company** . . . is far too generalized (and generalizable) to allege the proper ‘concrete and personal’ benefit required by the Second Circuit.”) (emphasis added); *id.* (“‘[A] desire to raise much needed capital’ [is] amongst the broadest, most generalized, and most commonplace motives of corporate motivation for any action”) (citing *In re Gilat Satellite Networks, Ltd.*, No. 02-CV-1510(CPS), 2005 WL 2277476, at \*19 (E.D.N.Y. Sept. 19, 2005));
- *Hawaii Structural Ironworkers Pension Trust Fund v. AMC Entm’t Holdings, Inc.*, 422 F. Supp. 3d 821, 849 (S.D.N.Y. 2019) (“Nor are Plaintiffs’ allegations that [defendants] believed a successful SPO was **necessary to protect [defendant] from insolvency** sufficient. To the contrary, the ‘need to attract investors in order to pay down debt accruing . . . is insufficient to demonstrate scienter because it is common to most for-profit companies.”) (emphasis added);
- *In re OSG Sec. Litig.*, 971 F. Supp. 2d 387, 408 (S.D.N.Y. 2013) (desire to complete a securities offering that was “**critical to [the company’s] very survival**” does not constitute “a legally sufficient motive for [defendants] to commit securities fraud”) (emphasis added);
- *Gissin v. Endres*, 739 F. Supp. 2d 488, 499 (S.D.N.Y. 2010) (despite company’s “‘crippling’ liquidity problem,” desire to complete a securities offering did not support inference of scienter);
- *Coronel v. Quanta Capital Holdings Ltd.*, No. 07-CV-1405(RPP), 2009 WL 174656, at \*16 (S.D.N.Y. Jan. 26, 2009) (“[A] motive to maintain a financial rating **to protect the viability of the Company is not sufficient, under the law of this Circuit**, to establish a motive to commit fraud.”) (emphasis added).

Instead of following this Circuit’s extensive authority, the Court cited a single case from the Eastern District of Pennsylvania to support the proposition that “courts have found allegations of motive adequate where the company’s [sic] needed to fundraise to survive.” Dkt. 54, at 21 (citing *Frater v. Hemispherx Biopharma, Inc.*, 996 F. Supp. 2d 335, 350 (E.D. Pa.

2014)). Putting aside whether *Frater* itself even stands for the proposition that needing to raise capital to ensure the company's survival can alone support an inference of scienter,<sup>1</sup> there is no need to look outside the Second Circuit given the extensive authority described above.

Allegations of motives “generally possessed by most corporate directors and officers,” including motives to avoid bankruptcy or continue operating as a going concern, are insufficient as a matter of law to plead scienter. *Kalnit v. Eichler*, 264 F.3d 131, 139 (2d Cir. 2001). The SAC contains *no* allegations of motive other than the alleged motive to raise capital to avoid bankruptcy and continue operating as a going concern. Accordingly, Plaintiff has not adequately pled motive to commit fraud.

**B. The Order's Reliance on a “Plausibility” Standard to Infer Scienter is Also Clear Error**

The Court declined to dismiss Plaintiff's claims for failure to adequately plead scienter, repeatedly stating that it found Plaintiff to have “plausibly” alleged scienter. *See* Dkt. 54, at 2 (“Skiadas has plausibly alleged . . . that Defendants deliberately or recklessly misled investors”); *id.* at 19 (“Skiadas has plausibly alleged that Defendants acted with scienter.”); *id.* at 23 (“Skiadas has plausibly alleged that Defendants deliberately or recklessly misrepresented that the FDA agreed that it would approve EDSIVO to keep the company afloat.”); *id.* (“Skiadas has plausibly alleged a claim for securities fraud. . .”).

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<sup>1</sup> Other factors in *Frater* that are not present here further supported the court's finding that plaintiff had adequately pled scienter. In *Frater*, shortly before making the alleged misstatements, defendants sold 29.5 million shares of stock via an equity distribution agreement, after which an individual defendant persuaded the company's board that the stock sales triggered a change-of-control provision in his employment contract that led to him receiving a percentage of the stock sale proceeds as a bonus. The court found sufficient allegations of scienter when considering the individual defendant's change-in-control provision that gave him “*personal incentives* relating to a stock sale in a way that *departs from executives' typical compensation incentives*” together with the timing of the misstatements to directly coincide with the equity distribution agreement, and the fact that the company needed cash to finance an additional clinical trial. *Frater*, 996 F. Supp. 2d at 350 (emphasis added). No such additional motives were alleged here.

This finding is directly contrary to United States Supreme Court authority, which holds:

To qualify as “strong” within the intendment of [the PSLRA], we hold, an inference of scienter must be *more than merely plausible or reasonable*—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent.

*Tellabs*, 551 U.S. at 314 (emphasis added); *see also S. Cherry Street, LLC v. Hennessee Grp.*, 573 F.3d 98 (2d Cir. 2009) (“To meet the ‘strong inference’ standard, it is not sufficient to set out ‘facts from which, if true, a reasonable person *could* infer that the defendant acted with the required intent’ . . . Rather, . . . an inference of scienter . . . must be cogent and at least as compelling as any opposing inference of nonfraudulent intent.”) (citing *Tellabs*, 551 U.S. at 314). The Order’s reliance on a “plausibility” standard for pleading scienter is inconsistent with the PSLRA and controlling Supreme Court and Second Circuit precedent, and constitutes clear error.

The Order nowhere holds, nor could it given the allegations, that Plaintiff has pled particular, or indeed any, facts that give rise to a cogent and compelling inference of scienter. Instead, the Order refers to a single case from the Central District of California that has never been cited in this Circuit to find that statements about FDA approval are probative of scienter. *See* Dkt. 54, at 20 (citing *In re Mannkind Secs. Actions*, 835 F. Supp. 2d 797). Apart from being non-binding, the facts of *Mannkind* make plain why Plaintiff here has not adequately pled scienter under the controlling standard.<sup>2</sup>

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<sup>2</sup> The Order disregarded numerous other distinctions between this case and *Mannkind* on scienter raised in Defendants’ motion to dismiss papers, including the fact that Mannkind had a specific incentive to maintain its share price at above \$6.50 per share due to its “unique financing arrangement” with a private investment partner (835 F. Supp. 2d at 803); that Mannkind repeatedly changed its characterization of its communications with the FDA during the course of litigation (*id.* at 809-10); and that the court found, based on the fact that Mannkind had been sued for fraud and scientific misconduct in connection with the data submitted to the FDA, that Mannkind had a “pattern of being less than forthright with its investors concerning . . . the FDA approval process.” *Id.* at 818-19. There are *no* such allegations here that would provide any basis for a strong inference of scienter.

The *Mannkind* court found that the plaintiff had adequately pled scienter based on the defendants' repeated, clear, *unambiguous* statements that the FDA had approved and agreed to the defendants' methodology, including that the FDA had "blessed, vetted, approved, accepted, and agreed to" the defendants' study methodology. *Id.* at 809. Here, by contrast, the Court's determination on scienter was premised on the Court "assum[ing]" that Defendants' ambiguous statements referred to approval of the NDA. *See* Dkt. 54, at 19. As discussed above, ambiguity is insufficient to plead falsity. It provides even less support for scienter, where plaintiffs must plead a cogent and compelling inference.

Indeed, under the PSLRA's heightened pleading standard and Supreme Court and Second Circuit precedent, "ambiguities count *against* inferring scienter." *Tellabs*, 551 U.S. at 326 (emphasis added). *See also Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital Inc.*, 531 F.3d 190, 194 (2d Cir. 2008) ("While we normally draw reasonable inferences in the non-movant's favor on a motion to dismiss . . . the PSLRA, which governs scienter pleading in securities fraud actions, establishes a more stringent rule for inferences involving scienter."); *Campaniello Imports, Ltd. v. Saporiti Italia S.p.A.*, 117 F.3d 655, 664 (2d Cir. 1997) ("Given the ambiguous nature . . . of each of the three factual assertions, the allegations, even taken together, are insufficient to raise a *strong* inference of fraudulent intent."); *In re Avon Sec. Litig.*, No. 91-CV-2287(LMM), 2004 WL 3761563, at \*12 n.18 (S.D.N.Y. Mar. 29, 2004) (dismissing claim for market manipulation in violation of Rule 10b-5 in connection with ambiguous offering circular, noting that "any claim based on the fact of ambiguity would fail on the ground of lack of scienter"). Accordingly, under the appropriate pleading standard, this Court's finding that "Defendants' statements about what the FDA 'agreed to' are ambiguous" itself supports a finding that Plaintiff *has not* adequately pled scienter. Dkt. 54, at 19.

Moreover, just three weeks ago, the Ninth Circuit (the same Circuit in which *Mannkind* was decided) affirmed dismissal with prejudice of a securities fraud class action against a biotechnology company on scienter grounds for the same reasons this case should be dismissed. *See Nguyen*, 2020 WL 3069776. Notably, the Ninth Circuit did not even mention *Mannkind* in *Nguyen*, let alone cite to it as authority. In *Nguyen*, like here, the plaintiff alleged that the defendants knew the FDA would not approve the medical device application in question because of alleged flaws in the clinical trials, but lied to the market to say otherwise. The challenged statements in *Nguyen* were far more definitive than those in this case, with the defendants allegedly expressly stating that FDA approval of the device was expected on a specified timeline. Yet the Ninth Circuit held that the proffered theory of scienter was implausible, particularly given the absence of stock sales or other evidence of personal financial gain to the individual defendants:

These allegations encounter an immediate first-level problem: why would defendants promise the market that the FDA would approve Nellix if defendants knew the FDA would eventually figure out that Nellix could not be approved . . . The theory does not make a whole lot of sense. It depends on the supposition that defendants would rather keep the stock price high for a time and then face the inevitable fallout once Nellix’s “unsolvable” migration problem was revealed. If defendants had sought to profit from this scheme in the interim, such as by selling off their stock or selling the company at a premium, the theory might have more legs. There are no factual allegations like that here. Instead we are asked to accept the theory that defendants were promising FDA approval for a medical device application they knew was “unapprovable,” misleading the market all the way up to the point that defendants were “unable to avoid the inevitable.” *The allegation does not resonate in common experience. And the PSLRA neither allows nor requires us to check our disbelief at the door.*

*Id.* at \*8 (emphasis added).

Similarly here, the Court is asked to accept the theory that Defendants promised FDA approval for a drug they knew would not be approved, in order to raise capital in the short term and face the inevitable fallout once it became apparent that the FDA had never agreed to approve the NDA. Leaving aside the fact that “not wholly illogical” (*see* Dkt. 54, at 22-23) is not the



standard by which to measure the adequacy of scienter allegations, *Nguyen* and numerous cases in this Circuit show why the theory Plaintiff asserts in the SAC is in fact not even plausible, let alone cogent or compelling. *See, e.g., Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124 (2d Cir. 1994) (“In looking for a sufficient allegation of motive, we assume that the defendant is acting in his or her informed economic self-interest. It is hard to see what benefits accrue from a short respite from an inevitable day of reckoning.”); *In re Loral Space & Commc’ns Ltd. Sec. Litig.*, No. 01-CV-4388(JGK), 2004 WL 376442, at \*7 (S.D.N.Y. Feb. 27, 2004) (“[T]he plaintiffs’ argument that [defendant] was motivated to engage in fraud to protect his professional reputation—when there was substantial risk that any such fraud would eventually be disclosed—is, at the very least, strained.”); *see also Nguyen*, 2020 WL 3069776, at 4 (finding implausible the allegation that “the company was quixotically seeking FDA approval for a medical device application it knew was destined for defeat”).

And it is certainly not “*at least as likely*” as the opposing inference that Defendants sincerely believed that the EDSIVO NDA would be approved and were acting accordingly. *Tellabs*, 551 U.S. at 328. *See also Gillis v. QRX Pharma Ltd.*, 197 F. Supp. 3d 557, 600 (S.D.N.Y. 2016) (finding “implausible” an alleged scheme in which defendant pharmaceutical company “continued to invest substantial time and resources in clinical studies and NDA submissions that it knew were doomed to fail, all the while misrepresenting to the public that approval was likely”). Here, as the allegations in the SAC themselves make clear, Defendants spent significant time and resources to hire personnel and prepare for a commercial launch of EDSIVO, hardly the actions of a company that knew its drug would not be approved. SAC ¶¶ 37, 94-99; *see also* Dkt. 50, at 20.



## CONCLUSION

The Order applied clearly erroneous standards for the pleading of falsity and scienter, and relied on irrelevant, non-binding case law while disregarding controlling law. Correction of any one of these errors should result in dismissal of the SAC. Accordingly, Defendants respectfully request that the Court reconsider the June 16, 2020 Order to the extent it denied Defendants' Motion to Dismiss the Second Amended Complaint.

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